DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700

91128d

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-51

April 10, 2001

Susan M. Baker, President
Skintech 2000, Inc.
4861 Dixie Highway, Suite 9
Fort Lauderdale, Florida 33334

Dear Ms. Baker:

During an inspection of your firm by the Food and Drug Administration (FDA) on November 13 and December 5 and 15, 2000, it was determined that your firm markets "Blue Cap Spray," which is labeled or promoted for the relief of chronic skin disorders such as psoriasis, eczema, and dermatitis. The product label and promotional material (labeling) distributed with "Blue Cap Spray," bear claims that this product is "for the relief of skin and scalp itching, irritation, redness, flaking, and scaling associated with dandruff and seborrheic dermatitis" and "exerts a high anti-bacterial and anti-fungal action." According to the label, the product contains among other things, isopropyl myristate, alcohol, and zinc pyrithione.

"Blue Cap Spray" is subject to the final regulations on Drug Products for the Control of Dandruff, Seborrheic Dermatitis and Psoriasis under Title 21 of the Code of Federal Regulations, Part 358, Subpart H (21 CFR 358, Subpart H), which became effective on December 4, 1992. This product fails to meet all the requirements of these final regulations. Since zinc pyrithione is not generally recognized as safe and effective for over-the-counter (OTC) use in treating psoriasis (21 CFR 358.710) nor so recognized for any OTC topical use when combined with undeclared corticosteroids (i.e., betamethasone-17-propionate, betamethasone-17-propionate-21-butyrate, and betamethasone-17-propionate 21-stearate), as determined by FDA's laboratory analysis. Therefore, "Blue Cap" is a "new drug" under section 201(p) of the Act. A "new drug" may not be legally marketed in the United States without an approved New Drug Application as required by section 505(a) of the Act. Because of the presence of betamethasone-17-propionate, betamethasone-17-propionate-21-butyrate, and betamethasone-17-propionate-21-stearate in the formulation, "Blue Cap Spray" is adulterated under section 501(c) of the Act.

"Blue Cap Spray" is misbranded under section 502(f)(1) in that its labeling does not bear adequate directions for use as described under 21 CFR 358, Subpart H, and the adequacy of the labeled directions for other uses has not been established. This product is misbranded under section 502(a) of the Act because its labeling is false and misleading to the extent that it suggests the product is safe and effective for its intended uses, when in fact, this has not been established.

This letter is not intended to be an all-inclusive review of all labeling and products your firm might market. As a distributor and labeler, you are responsible for assuring that products that you distribute and label are safe and effective for their intended uses. We note that you voluntarily relinquished the "Blue Cap Spray" remaining at your facility to the FDA investigator at the time of the inspection. We also note that you have also ceased distributing "Blue Cap Cream," which is listed in your promotional literature.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to preclude these violations from occurring in the future. If you continue to label and distribute products that violate the Act as described above, FDA may consider initiating regulatory action, such as seizure or injunction, without further warning.

Your reply should be sent to the attention of Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

Emma R. Singleton
Director, Florida District